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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,894

09/16/2003

Chi-Ming Che

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4526

32172

7590

10/05/2007

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/663,894

Applicant(s)

CHE, CHI-MING

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/9/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,7,9-11,13,25-28,30,31,33-35,37,55,58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,9-11,13,25-28,30,31,33-35,37,55,58 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The response filed **7/17/07** presents remarks and arguments to the office action mailed **5/16/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of claims

Claims 1-4, 6-7, 9-11, 13, 25-28, 30, 31, 33-35, 37, 55, 58 and 59 are pending.

Claims 1, 25, 55, and 58 are amended.

Claims 5, 8, 12, 14-24, 29, 32, 36, 38-54, 56-57 and 60-63 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-7, 9-11, 13, 25-28, 30, 31, 33-35, 37, 55, 58 and 59 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 recite the limitation of m as -3 to 1 , there is no 1 in the teaching of m ; and there is nowhere in the specification where in it is stated the n is equal to the absolute value of m/p when p is not equal to zero or n is equal to zero, when p is equal to zero.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant argues that the wheelhouse et al., teach away from the claimed invention which uses the composition containing gold (III) porphyrins that exhibit potent cytotoxicity, with emphasis on the effective telomerase inhibitors have low cytotoxicity against tumor cell lines.

Applicant is arguing what is not set forth in the claim. The low toxicity of the compounds are not set forth in the claims, therefore it carries no weight. What is

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claimed is method of induction of cytotoxicity effect in hepatocellular or nasopharyngeal carcinoma. The compound is known to give a cytotoxic effect. Thus the claim limitation is met by inducing cytotoxicity, whether low or high does not carry any weight. The claims do not recite what amount of cytotoxic effect the claimed compound establishes.

From the remarks made especially on page 12 last paragraph and page 13 first paragraph, it appears that Applicant is trying to say that the compounds of the instant application are more superior over the compounds of Wheelhouse et al. If this is so, then there must be a showing of unexpected results comparing the Wheelhouse et al., compounds with that of the claimed compound.

Next, Applicant argues that the claims now specifically teach induction of cytotoxic effects in hepatocellular carcinoma or nasopharyngeal carcinoma.

Telomerase is a specialized ribonucleoprotein polymerase that adds hexanucleotides (TTAGGG) onto human chromosomal ends. The expression of telomerase activity has been associated with cell immortalization and the malignant phenotype in most cancers (as evident by Ku et al., BioChem. And Biophys. Res. Comm. See underlining). The Wheelhouse et al., teach New porphyrin telomerase inhibitors - used in modifying telomerase or telomere function and for inhibiting cell preferably cancer cell proliferation. Thus one of ordinary skill in the art would be motivated to use the compound of Wheelhouse et al to treat a wide variation of cancers, since it is known that telomerase activity is found in most cancers. To further support that the compound can be used in hepatocellular cancer, Suda et al., Hepatology teach because telomerase activity is necessary for cell immortality and probably associated

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with tumor progression, we have evaluated a possible aid for quantization of the activity to predict intrahepatic recurrences after surgery in patients with hepatocellular carcinoma (HCC).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

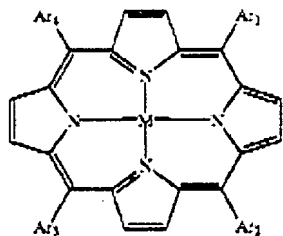
In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. The rejection is maintained and repeated below, thus the argument is found unpersuasive.

Claims **1-4 and 58-59** remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wheelhouse et al. US 6,087,493.

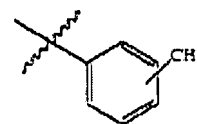
Instant claim 1 is directed to a method for induction of apoptosis of cancer cells, comprising administering to a patient a metal porphyrin (Wheelhouse et al. see col. 4, lines 35-50), wherein the metal is gold (III) (Wheelhouse et al. see col. 4, lines 50-51)

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complex

wherein instantly claimed R(1, 4, 7 and 10) are Aryl (1, 4, 7 and 10) (Wheelhouse et al. see col. 4, lines 35-50), R(2, 3, 5, 6, 8, 9, 11, and 12) are hydrogen as in instant claims 1-2 and 58-59. Absent factual evidence when a carbon is given no substituents it is a hydrogen taken into account the bonds since carbon can form four bonds) and the counter ion is a pharmaceutical preparation (Wheelhouse et al. see col. 4, lines 54-55). And with regards to the instant claim 3, the reference teaches R(1, 4, 7 and 10) is Aryl. An aryl as referred to be a functional group derived from a simple aromatic ring a phenyl (as defined by cancerweb.ccl.ac.uk enclosed) wherein the aryl is a phenyl (see col. 4, lines 60-65), wherein the phenyl is optionally-4methylphenyl (Wheelhouse et al. see col. 5, lines 10-15). Although the



reference suggests the methyl group in various positions as in

it

however, teaches from the structure that the methyl group is capable of attaching to any of the positions and one possible position is the para (fourth position) as in claim 4. The (Wheelhouse et al. see abstract) teach these compounds are been used in developing cancer treatments and used in the treatment of cancer (Wheelhouse et al. see col.s 15, line 10-15 and 38, lines 42-55) and are effective telomerase inhibitors and have an effect in modulating tumor proliferation and mortality in animal models (Wheelhouse et

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al. see col. 2, lines 6-26 and also lines 38-41). Thus teaches apoptosis as claimed in the instant claim 1.

As to instant claims 58-59, wherein a complex is formed between a ligand and a gold(III) complex, Wheelhouse et al. teach a complex is formed (see col. 11, lines 60-61) wherein the complex consist of a porphyrin and a metalloporphyrin as in claim 59, thus claim 58 the formation of a complex is obvious.

One of ordinary skill in the art would have been motivated to use the teaching of the above reference Wheelhouse et al. and induce apoptosis to cancer cells as claimed because the references teaches the use of types of metal porphyrins in the treatment of cancer at the time the claimed invention was made. With regards to the formation of complex, one of ordinary skill in the art would have been motivated to use the teaching of Wheelhouse et al. formed a complex as taught and used at the time the instant claim was invented because the reference teaches so. Also, Wheelhouse et al., teach, inhibition of telomerase activity vial G-quaddruxplex structure, via stabilizing or disrupting formation of such G-quadruplexes. G-quadruplexes are polynucleotides (see col. 2, lines 30-41).

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/25/07

Ardin H. Marschel 9/30/07
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SUPERVISORY PATENT EXAMINER